K100857

John J Riccio (Fusion Medical Corp.)
44 Church St
West Haven CT. 06516

Phone: (203) 823-8511
Fax: (860) 454-7562

MAY 2 7 2010

Summary
Fusion Medical Ring Lock System

Date Of submission:	3/12/10
Type of submission:	510(K)
Reason for submission:	New Device
Product code:	KTT, CRF-21 888.3030
Device class:	II
Classification panel:	Orthopedics
Predicate devices: K052196	Vilex
Common Name:	External Ring Fixation
Device Trade Name:	Fusion Medical Ring Lock System
Establishment Operations:	Manufacture
Indications for use:	Stabilization of fractures & Osteotomy Bone deformity correction of lower extremities. Arthrodesis of the rear foot, mid foot and ankle joint. Limb lengthening in pediatric and adults.
Submitter:	John Riccio

Device Description:
The Fusion Medical Ring Lock system is a Circular Frame and Footplate system, used in lower extremity Stabilization and Deformity Correction. Wires are placed in the bone and attached to the frame with wire fixation bolts. The wires are then tensioned to support the bone. Rings are made of aluminum 6061 T6. Posts are used to capture wires that are elevated off the frame. Posts are made of 17-4 PH stainless steel. Washers are used to fine tune the elevation, and hinges are used for gradual correction of bone.

Technological Characteristics:
The technological characteristics between the Vilex Frame (K052196) and the Fusion Frame are identical, the only design difference is our tabs on the rings have 3 holes; Vilex has 2 holes on their tabs. Both are made from the same material, aluminum alloy. The Vilex Frame has the same sizes as the Fusion Frame: 140mm, 160mm, 180mm, and 205mm. Rods are the same material and length, as are other components. The Vilex x-fix frame has the same indication for use.

Summary of Testing:
Cross sectional engineering analysis shows the Fusion Medical Ring Lock system is equivalent to the Vilex Frame. There was no change to the design or size to decrease structural strengths in the rings or components and their material.

Conclusion:
Fusion Medical Ring Lock System is equivalent to devices already marketed for the same indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. John J. Riccio
44 Church Street
West Haven, Connecticut 06516

MAY 2 7 2010

Re: K100857
Trade/Device Name: Fusion Medical Ring Lock System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: March 12, 2010
Received: March 26, 2010

Dear Mr. Riccio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K100857

Device Name: Fusion Medical Ring Lock System

Indications for Use: Stabilization of fractures & Osteotomy Bone deformity correction of lower extremities Arthrodesis of the rear foot, mid foot, and ankle joint. Limb lengthening in pediatric and adults.

Prescription Use X AND /OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please Do Not Write Below This Line-Continue On Another Page Of Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100857

p. 1 of 1